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| EXAMINER | |
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| BUCKLEY, AUDREA | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/623,864 | SCHACHT ET AL. | |
| | Examiner | Art Unit | |
| | AUDREA J. BUCKLEY | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

Acknowledgement is made of Applicant's claim amendments and remarks/arguments filed 7/2/2010.

Claims 1-6 and 8-13 are pending and under consideration herein.

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/2010 has been entered.

### *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on 7/2/2010 was filed after the mailing date of the final office action on 1/6/2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### *Withdrawn Claim Rejections*

The rejection of claims 1-6 and 8-13 under 35 U.S.C. 103(a) as being unpatentable over D'Angelo et al. (US 5,932,240) in view of Lauterbach (US 2003/0027793 A1) is withdrawn in light of Applicants' amendments to the claims filed 7/2/2010.

***New Grounds of Rejection as Necessitated by Amendment***

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-6, and 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Lauterback (US Patent Application No. 2003/0027793 A1).**

The applied reference has common inventors Schacht and Wolff with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lauterback et al. teach a silicone adhesive-based transdermal therapeutic system (TTS) comprising rotigotine as the active ingredient wherein it was shown that a rotigotine free base form in a silicone matrix provided desirably high plasma levels of rotigotine (see abstract; paragraph [0014]). Lauterback exemplifies a transdermal

therapeutic system using a combination of silicone-type pressure sensitive adhesives, wherein rotigotine was present in free base solution (346.4 g) in ethanol and polyvinyl pyrrolidone as a preferred solubilizer (see [0039]-[0041] and [0022]). Lauterback teaches that a preferred content of rotigotine per patch is in the range of 0.1 to 2 mg per $cm^2$ ([0027]). Lauterback teaches a polyester release liner (SCOTCHPAK 1022 ([0040]) as well as a backing layer that is inert with respect to the constituents of the matrix, and a self-adhesive matrix layer containing an effective quantity of rotigotine or rotigotine hydrochloride. The system further comprises a protective film which is to be removed before use. The matrix system is composed of a non-aqueous polymer adhesive system, based on acrylate or silicone; and wherein said matrix is essentially free of inorganic silicate particles (page 2, [0011]). It is noted that this embodiment of the invention utilizes rotigotine in its free base form and is permeable to the free base of rotigotine (see [0044]).

Regarding the microreservoirs and their instantly recited maximum diameter and substantial impermeability to the protonated form of rotigotine as in pending claim 1, Lauterback et al. does not explicitly disclose these characteristics. However, the Lauterback therapeutic system is made by making an ethanolic solution of free base rotigotine then mixing this solution with polyvinylpyrrolidone, two silicone adhesives, and adjuvants to obtain a homogenous dispersion (see [0038] and [0039]). It is noted that this method of making is the same as in Example 1 (page 14 of the specification) of the instant invention. More specifically, adjuvants aqueous sodium bisulfite solution, ascorbyl palmitate, DL-alpha-tocopherol, BIO-PSA Q7-4301, and BIO-PSA 4201 as

used in [0039] of the Lauterback reference are exactly the same as used in instant Example 1 (page 14 of the specification). MPEP 2112.02 indicates that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Since these formulations are made using the same components and the same method, the formulation of Lauterback is considered to have permeability and microreservoir characteristics as in "(2),(4), and (5)" of pending claim 1, absent evidence to the contrary. Likewise, the example of Lauterback is considered to have had the mean diameter characteristics of pending claims 2, 12, and 13, as well as the microreservoir concentration of claims 10 and 12, and the absorption capability of pending claim 3, absent evidence to the contrary. That is, the matrix interstices would have been the same in the Lauterback reference and the instant invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-4, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (US 5,788,983, issued Aug. 1998) in view of Muller et al. (WO 99/49852, English language equivalent US Pat. 6,884,434 cited below).**

Chien et al. teach the controlled delivery of transdermally administered active agents. The transdermal device comprises a backing layer which is impervious to the ingredients of the dosage unit, a reservoir, and an adhesive means to affix the dosage unit to the skin (see column 2, lines 28-48). It is taught that when the pharmaceutical is present in the reservoir in the form of microreservoirs, the pharmaceutical can be dissolved in a biocompatible liquid which can provide desired variability of transdermal absorption. The pharmaceutical can be dissolved or dispersed in the liquid before being dispersed into a biocompatible polymeric material such as an adhesive polymer and then stirred to form a pharmaceutical containing polymeric material wherein microreservoirs of the dissolved pharmaceutical are dispersed in a polymeric material (see column 4, lines 1-16); Chien et al. teaches that a number of adhesive polymers can be used including polyacrylates, silicone elastomers, polyisobutylene, and the like (see column 9, lines 23-25). The backing layer can be made of any suitable material which

is impermeable to the pharmaceutical dispersed within the adjacent reservoir layer (column 6, lines 33-35). The polymer material selected must permit the pharmaceutical to be released for the desired transdermal absorption. The reservoir medium containing dissolved/dispersed pharmaceutical and the polymer material are combined to cause the microreservoirs to be formed and homogeneously dispersed in the polymeric material. As to claims 2, 12, and 13, the microreservoirs have a diameter between 2 and 200 microns, preferably between 5 and 100 microns (see column 9, lines 25-27); it is noted that a prima facie case of obviousness exists where the prior art teaches an overlapping range (see MPEP 2144.05). In example 3, for instance, the adhesive formulation comprising the active agent is applied at a thickness of 500 microns which dries to a thickness of 220 microns (column 24, line 23); therefore, the thickness of the adhesive matrix is greater than the maximum diameter of the microreservoirs.

As to claim 1, although Chien et al. teach that any pharmaceutical can be used in the invention (column 11, lines 14-63), Chien et al. does not teach rotigotine as a particular pharmaceutical active agent.

However, Muller et al. teach transdermal systems containing a D2 agonist for the treatment of Parkinson's disease (column 1, lines 9-10). The simplest forms of drug delivery matrices include a backing layer, an active substance containing self-adhesive matrix, and a protective film to be removed prior to use (see column 2, lines 51-56). The adhesives are either acrylate or silicone based (column 2, lines 36-37) and include silicone adhesives, for example, BIO-PSA Q7-4301 and BIO-PSA Q7-4201 (see column 6, lines 10-12) Further regarding claim 4, due to the basic nature of rotigotine (5,6,7,8-

tetrahydro-6-[propyl-2-(2-thienyl)ethyl]amino-1-naphthalenol), silicone adhesives that are amine-resistant are used (column 3, lines 1-10). It is taught that for silicone adhesives only the active substance base (free base form) is suitable for use as salts thereof (protonated form) are practically insoluble in these types of adhesives. Additionally, it is taught that if polyvinylpyrrolidone is added to the adhesive, the dissolving capacity for the free base in such matrices is desirably increased (column 3, lines 55-67). Additionally, since the microreservoirs are dispersed in the polymeric adhesive, the diameter of the microreservoirs necessarily would have been less than the thickness of the adhesive matrix.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement rotigotine free base and silicone adhesives as taught by Muller et al. in the transdermal devices of Chien et al. One would have been motivated to do so since Chien teaches that any pharmaceutical agent can be delivered and since Muller teaches rotigotine actives administered by silicone adhesives. Furthermore, the selection of a specific drug is considered prima facie obvious depending on the desired condition/symptoms to be treated, so that it would have been prima facie obvious to utilize rotigotine based as taught by Muller et al. to treat Parkinson's disease.

Regarding claim 3, it is further noted that Muller et al. teach that the polymer adhesive system comprising rotigotine is substantially free of inorganic silicate particulates (see column 2, lines 39-40), which the instant specification identifies on page 9 as an example of particles that can undesirably absorb salts of rotigotine.

Regarding claims 8 and 9, it is noted that Muller et al. teach polyvinylpyrrolidone as an amine-resistant silicone adhesive increasing the rotigotine solubility (crystallization inhibitor). Regarding claims 10 and 11, Muller et al. teach BIO-PSA Q7-4301 and BIO-PSA Q7-4201 by Dow Corning to be recommended amine-resistant silicone adhesives (see column 6, lines 10-12). Where these are the same preferred adhesives of the instant specification (see page 10, lines 30-34), these adhesives necessarily would have had the instantly recited matrix holes/interstices serving as microreservoirs in which the rotigotine was contained.

**Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (US 5,788,983) in view of Muller et al. (WO 99/49852) as applied above, and further in view of Pfister et al. (US Pat. 5,232,702, issued Aug. 1993).**

The teachings of Chien and Muller et al. are delineated above. Neither of these references teaches the combination of silicone pressure sensitive adhesives as instantly recited.

However, Pfister teaches silicone pressure sensitive adhesive compositions for transdermal drug delivery. Generally, Pfister teaches that a suitable class of silicone pressure sensitive adhesives consists of a silanol polydiorganosiloxane and a polysilicate resin (see column 3, lines 10-18). Pfister teaches that the implementation of silanol radicals in silicone pressure sensitive adhesives provides desirable improvement in the cohesive-strength of the adhesive (see column 4, lines 1-3) and that the silicone pressure sensitive adhesives disclosed are tacky to the touch (see column 4, line 50).

Example B (column 13) teaches that an adhesive formulation consisting of a low silanol-containing amine compatible silicone adhesive (Adhesive II) and a high silanol-containing silicone adhesive (adhesive I) were prepared.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Chien et al., Muller et al, and Pfister et al. and to utilize a combination of a low silanol containing amine-compatible silicone adhesive and a high silanol containing silicone adhesive as taught by Pfister in place of the silicone-based polymer adhesives taught by Muller et al. One would have been motivated to utilize this combination of silanols in order to reduce flow and improve creep resistance and therefore adhesive properties as taught by Pfister.

**Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (US 5,788,983) in view of Muller et al. (WO 99/49852) and Pfister et al. (US Pat. 5,232,702, issued Aug. 1993) as applied above and further in view of Kosal (US 2003/0065086 A1, filed Oct. 2001).**

The teachings of Chien, Muller, and Pfister are delineated above. As to claim 6, it is noted that Muller et al. teach BIO-PSA Q7-4301 and BIO-PSA Q7-4201 as suitable amine-resistant silicone adhesives where silicone adhesives in particular are desirable in combination with active substance base forms on account of the solubility characteristics of the base form (see column 3, last paragraph). It is further noted that Pfister teaches polydimethylsiloxane (polysiloxane) components in pressure sensitive adhesives deemed most practical for the disclosed invention (see column 4, lines 6-10).

Pfister further teaches polydimethylsiloxanes combined with a resin for the adhesive disclosed (see column 4, line 28). These references do not specify a blend of pressure sensitive adhesives as instantly recited.

However, Kosal teaches silicone pressure sensitive adhesive compositions such as those used in medical and personal care applications (see [0004]). These adhesives deliver performance properties such as controlled tack such as in transdermal drug delivery patches (see [0027]). Examples 2-4 teach a combination of a low tack pressure sensitive adhesive ("PSA") and medium tack pressure sensitive adhesive (see steps "(i)" and "(iii)" of [0034]). It is specified that the high tack PSA contains polydimethylsiloxane and resin, as does the medium tack PSA (see [0034]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the high tack silicone PSA comprising a polysiloxane and resin with a corresponding medium tack PSA as taught by Kosal in the formulations of Chien, Muller, and Pfister. One would have been motivated to do so to control the tack and therefore the performance properties of the pressure sensitive adhesives, as taught by Kosal, and as a normal part of routine scientific inquiry and optimization.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-6 and 8-13 provisionally are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 10-13, 15-18, and 20-23 of copending Application No. 10/627,990 in view of Muller et al. (WO 99/49852, English language equivalent US Pat. 6,884,434 cited below).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to a transdermal delivery system comprising a backing layer, a self-adhesive matrix comprising an active ingredient, and a matrix comprised of a semi-solid or semi-permeable polymer. The difference between the co-pending transdermal delivery system is that it incorporates active agents fentanyl or oxybutynin rather than rotigotine as in the instant application. It would have been within the skill of the ordinary artisan to substitute active agents since the selection of a specific drug is considered prima facie obvious depending on the desired condition/symptoms to be treated, and since Muller et al. teaches rotigotine bases actives in transdermal devices to treat Parkinson's disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1, 3-6, 8 and 9 provisionally are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 17, 18, 19, and 27-30 of copending Application No. 10/139,894, the application associated with "Lauterback", PG Pub 2003/0027793 A1 applied above.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to a transdermal delivery system comprising a self-adhesive matrix comprising an active ingredient, a matrix comprised of a tacky pressure-sensitive adhesive comprised of at least two silicone pressure adhesive components (high and low tack as in the copending claims), a

polyvinylpyrrolidone solubilizer, and minimal inorganic silicates or non-free base forms of rotigotine. The difference between the pending claims and the copending claims is that the pending claims require a backing layer of the transdermal device, while the copending claims are drawn to a method of treating a subject by administering the active agent from a specified silicone pressure sensitive adhesive matrix; however, it would have been within the skill of the ordinary artisan to administer rotigotine active agent from a transdermal device having a backing to the adhesive substrate, as such devices were commonly used in the transdermal patch art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicant's arguments presented 7/2/2010 have been fully considered but are moot in light of amendment. As noted above, all rejections previously presented and not re-iterated herein are withdrawn. Applicant's positions against cited references are summarized and responded to as follows.

In reply, Applicant's arguments have been fully considered but are not persuasive. Applicant takes no position against the relevance of Lauterback. Applicant's arguments against Lauterback rely on D'Angelo reference. The rejection relying on D'Angelo has been withdrawn. Lauterback teaches pressure sensitive adhesives forming a matrix in which other components are embedded; Lauterback teaches rotigotine in particular as a pharmaceutical active implemented into the

adhesive networks disclosed (see [0016] and [0017]). Specifically, Lauterback teaches rotigotine in free base form provides high plasma levels of active agent and therapeutic progress in the transdermal treatment of Parkinson's disease; Lauterback attributes this success to the size of the free base form being relatively small compared to an alternative (salt) form (see [0014], [0031]). Therefore, Lauterback teaches the size/free base limitations as instantly recited and remains a relevant reference.

***Conclusion***

No claims are found allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635